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| EXAMINER |
|---|
| KERR, KATHLEEN M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | 12 |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/019,817 | GERMOND ET AL. | |
| | Examiner | Art Unit | |
| | Kathleen M Kerr | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20,21,27,28,31 and 38* is/are allowed.

6)☒ Claim(s) *23,25,26,30,32-34 and 37* is/are rejected.

7)☒ Claim(s) *22,24,29,35 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Application Status*

1. In response to the previous Office action, a non-Final rejection (Paper No. 10, mailed on March 21, 2003), Applicants filed a response and amendment received on June 26, 2003 (Paper No. 11). Said amendment cancelled Claims 1-19 and added new Claims 20-38. Thus, Claims 20-38 are pending in the instant Office action and will be examined herein.

### *Priority*

2. As previously noted, the instant application is granted the benefit of priority for the European application 99112471 filed on June 30, 1999 and International Application No. PCT/EP00/05834 filed on June 23, 2000.

### *Compliance with the Sequence Rules*

3. As previously noted, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). A sequence listing in computer readable form and paper copy was filed on May 13, 2002 (Paper No. 5); said listing has been entered. However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

a) Figure 1 contains disclosure of DNA sequences without benefit of SEQ ID NOs.
b) Figure 2 contains disclosure of DNA sequences without benefit of SEQ ID NOs.
c) Figure 3 contains disclosure of DNA and protein sequences without benefit of SEQ ID NOs.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Applicants responded to the previous request to comply with the sequence rules by noting "Figures 1-3 are sufficiently described"; however, this is not at issue. Nucleotide sequences of ≥10 nucleotides and amino acid sequences of ≥4 residues must comply with the sequence rules as noted above. Appropriate correction is required.

***Withdrawn - Objections to the Specification***

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment to the title.

5. Previous objection to the specification for not containing an abstract is withdrawn by virtue of Applicants' amendment.

6. Previous objection to the specification for inconsistencies is withdrawn by virtue of Applicant's amendment deleting all of said inconsistencies.

***Maintained - Objections to the Specification***

7. Previous objection to the specification for being confusing with respect to the sequence listing since the sequence listing contains 22 sequences as filed on May 13, 2002 (Paper No. 5) and every SEQ ID NO is mentioned in the specification and/or the claims except SEQ ID NO: 22 is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the specification is clear without any description of SEQ ID NO:22 except for its listing in the sequence listing. The Examiner fails to see how this explains the inclusion of SEQ ID NO:22. Its inclusion is the sequence listing is confusing and must be described in the specification. Correction and/or clarification are required.

***Status of Previously Pending Claim Objections/Rejections***

8. All previously pending claim objections and/or rejection are withdrawn by virtue of Applicant's cancellation of all previously pending claims. Wherein the new claims have not obviated the previously proposed objection/rejections, Applicants arguments will be addressed below with new objections/rejections.

**NEW OBJECTIONS/REJECTIONS**

***Claim Objections***

9. Claim 22 is objected to for a spelling/typographical error. The word "reserved" should be "reversed" as previously found in the claims. Correction is required.

10. Claims 24, 35, and 36 are objected to for depending from a rejected claim.

11. Claim 26 is objected to for a spelling error. The word "indentified" is misspelled. Correction is required.

12. Claim 29 is objected to for having improper plural species noted. The term "a lactic acid bacteria" is improper. The term must recite either ---a lactic acid bacterium--- or ---lactic acid bacteria--- for clarity.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 23 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "The definition of the term "functional peptides" is unclear. All peptides have some function, but this term would not limit the parent claim is given this broad interpretation. Perhaps a particular function or set of functions is intended? Clarification is required."

Applicants argue that "the term is sufficiently clear in meaning and scope as further supported by the specification." The Examiner wholly disagrees. As previously noted, all peptides have some function. Bacteriocins, hormones and insulin, as found in dependent Claim 24, are considered functional peptides; however, so is His-His-His-His-His-His for example since it binds metal ions. The specification does not further explain or define "functional peptides" other than by the examples in Claim 24. What kind of function is required? The

examples imply particularly useful functions well known in the art, but these limitations cannot be read into the claims. Thus, the metes and bounds of the term are wholly unclear in view of the implications of the art but the lack of definition in the specification.

14. Claim 25 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As previously noted, the "term "catabolite responsive elements" is unclear. In the specification, an example of a CRE is described on page 8, that is SEQ ID NO:8, which is embedded within SEQ ID NO:9, the promoter region required to be a part of the DNA sequence. It is unclear if this region must be deleted from the claimed sequence or if any and all CRE's must be deleted. If the latter is true, the nature of a CRE, so that it can be discerned by one of ordinary skill in the art as a part of SEQ ID NO:9, is unclear. Clarification is required."

Applicants argue the rejection of Claim 6 under 35 U.S.C. § 112, second paragraph, regarding its clarity for the term "catabolite responsive element". Applicants argue that the term is "an alternative expression for lac repressor". Firstly, the Examiner disagrees that this is an alternate term of art; this alternate term is nowhere equated in the specification. Applicants are invited to cite art wherein the terms are used interchangeably. Additionally, as previously noted by the Examiner, an example of a CRE sequence is SEQ ID NO:8 that is *embedded* in SEQ ID NO:9 (*not* an equal sequence), the full-length lac repressor described in the specification. Thus, the specification describes a CRE as a part of a lac repressor and not a full lac repressor as Applicants argue. Secondly, if CRE is an alternative term for lac repressor in its entirety as Applicants argue, is this to mean that presently pending Claim 25 could also be worded as ---

Claim 22 wherein y=0 or can any lac repressor be "devoid"? The metes and bounds of new Claim 25 are wholly unclear for these reasons.

15. Claim 30 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "incorporated into a microorganism's chromosome" is unclear. Which microorganism's chromosome? The recombinant microorganism as implied or some other microorganism's chromosome? If what is intended is to incorporate into the recombinant microorganism's chromosome, then the phrase should read ---incorporated into the microorganism's chromosome--- for clarity.

16. Claim 32 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "the DNA sequence" is unclear as to its antecedent basis in Claim 27, which recites a DNA expression construct containing a DNA sequence. Is the limitation in Claim 32 that the DNA sequence, itself required to be in an expression construct, be a plasmid? Or should Claim 32 read ---wherein the DNA expression construct is a plasmid---? Clarification is required.

The Examiner notes that Applicants' remarks describe a copy of deposit information for particular plasmids as recited in cancelled Claim 12, as if these plasmids were to be recited in new Claim 32. This is not the case.

17. Claims 33, 34, and 37 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. As previously noted, the specification describes the requirement of lactose for expression using the noted DNA constructs; said lactose binds the repressor protein inhibiting the binding of the repressor to the promoter region so that protein expression can take place. Thus, if claiming the production of the polypeptide of interest, addition of lactose is an essential method step that must be claimed. Correction is required.

18. Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "a microorganism's chromosome" is wholly unclear since the parent claim, Claim 33, only refers to a host cell. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claim 26 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As previously noted, Claim 26

"is drawn to DNA sequence that, optionally, is claimed solely by function ("or a functional variant") and without any structural limitations.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, genes encoding a lac repressor protein are described as any DNA sequence encoding SEQ ID NO:2. These genes are only described according to the functional characteristics of the enzyme they encode; no structural relationship is described or used in the claims. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Is there any required relatedness to a DNA sequence encoding SEQ ID NO:2? It is not required by the claim. Therefore, claims drawn to DNA containing the genus of said genes are also not adequately described. The

Examiner suggests adding a structural limitation to the claimed "functional variant" or deleting the term."

Applicants argue this rejection with respect to previous Claim 7 by arguing that the specification provides adequate written description based on the function disclosed. This is not the case as noted above in the rejection and as previously noted. Without any limitations on structure, all lac repressor proteins retaining lac repressor function require adequate written description. The specification provides a single example, SEQ ID NO:2. The specification provides no description of SEQ ID NO:2 such that one of skill in the art would recognize the crucial residues of the protein for retaining functionality. Thus, one of skill in the art would be unable to predict the structure of other members of the claimed genus. For these reasons, all previously of record, Claim 26 fails to satisfy the written description requirement under 35 U.S.C. § 112, first paragraph.

20. Claim 25 is rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for DNA sequences comprising SEQ ID NO:9 in the absence of the portion that is SEQ ID NO:8 (a catabolite responsive element or CRE), does not reasonably provide enablement for DNA sequences comprising SEQ ID NO:9 in the absence of some other portion of some other CRE sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To identify other CRE's in SEQ ID NO:9, considering a myriad of different catabolites, would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in

Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification presents no guidance or working examples for the identification of other CRE sequences within SEQ ID NO. No guidance of catabolites is presented as well. Numerous catabolites and portions of the sequence must be assayed to determine other CRE sequences. Such a discovery is wholly unpredictable in light of the information described in the instant specification in combination with the art. For these reasons, Claim 25 is not enabled to the full extent of its scope.

Applicants' arguments concerning the previously cited scope of enablement rejection with respect to this term are noted above related to the rejection under 35 U.S.C. § 112, second paragraph. Moreover, Applicants argue that the clarity of the term, still in question as noted

above, "should also allow one skilled in the art to practice the claimed invention without undue experimentation." The Examiner disagrees. Since a CRE is a portion of a lac repressor and the specification provides no guidance or working examples for the identification of other CRE's in SEQ ID NO:9 or elsewhere and their identification is wholly unpredictable, Claim 25 is not enabled to the full extent of its scope.

21. Claim 26 is rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for DNA sequences encoding SEQ ID NO:2, does not reasonably provide enablement for DNA sequences encoding functional variants of SEQ ID NO:2, the function being to bind SEQ ID NO:9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To identify functional variants of DNA encoding SEQ ID NO:2 would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized above.

The instant specification presents no guidance or working examples for the identification of novel proteins that bind SEQ ID NO:9. The nature of the invention, considering the three-dimensional structures of proteins, is such that any structure, even those wholly unrelated to SEQ ID NO:2, may bind SEQ ID NO:9. No description of the functionally required elements of SEQ ID NO:2 is found in the specification to aide the experimentation of one of skill in the art in making new, functionally similar proteins. Moreover, it is wholly unpredictable is such sequences exist naturally or if they can be engineered recombinantly. For these reasons, Claim 7 is not enabled to the full extent of its scope.

Applicants argue this rejection with respect to previous Claim 7 by arguing that the specification provides sufficient guidance to the skilled artisan to determine functional variants of SEQ ID NO:2. This is not convincing because the ability to "find" is not equivalent to the ability to "make" as required by the statute. As noted above, no description of the functionally required elements of SEQ ID NO:2 is found in the specification to aide the experimentation of one of skill in the art in making new, functionally similar proteins. For these reasons, the specification fails to satisfy the enablement requirement for the full extent of the scope of Claim 26.

***Summary of Pending Issues***

22. The following is a summary of the issues pending in the instant application:

a) The application does not comply with the sequence rules.
b) The specification stands objected to for being confusing about the presence of SEQ ID NO:22.
c) Claims 22 and 26 stand objected to for a spelling/typographical error.
d) Claims 24, 35, and 36 stand objected to for depending from a rejected claim.
e) Claim 29 stands objected to for having improper plural species noted.
f) Claim 23 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "functional peptides".
g) Claim 25 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "catabolite responsive elements".
h) Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "incorporated into a microorganism's chromosome".
i) Claim 32 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "the DNA sequence".
j) Claims 33, 34, and 37 stand rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps.
k) Claim 37 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "a microorganism's chromosome".
l) Claim 26 stands rejected under 35 U.S.C. § 112, first paragraph, written description.
m) Claim 25 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
n) Claim 26 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

***Allowable Subject Matter***

23. The following is reiterated from the previous Office action: "SEQ ID NO:9 is free of the prior art; said sequence is from the lac operon of *Lactobacillus delbrueckii* subsp. *lactis*. The promoter region, SEQ ID NO:9, is different among other subspecies of *L. delbrueckii* as evidenced in the specification and the post-filing date (Germond *et al*, 2003). Although portions of SEQ ID NO:9 may be taught in the prior art in the form of IS elements from the subspecies *bulgaricus*, the full-length of SEQ ID NO:9 is not taught in the prior art and is required in all the pending claims except Claim 7. Moreover, no evidence that the IS elements previously found were located as a part of SEQ ID NO:9 in subspecies *lactis*, with or without sequence information, as presented in the instant specification.

Any DNA sequence encoding SEQ ID NO:2 is also free of the prior art; SEQ ID NO:2 is a lac repressor protein from *Lactobacillus delbrueckii* subsp. *lactis* that is a part of the lac operon.

Leong-Morgenthaler *et al*. teach a lac operon from *L. delbrueckii* subsp. *bulgaricus* wherein the DNA sequence upstream of the permease gene, that is the same location as SEQ ID NO:9 taught in the instant specification, is similar (~75% identity) to SEQ ID NO:9; however, neither SEQ ID NO:9 nor isolated portions of the lac operon from subspecies *lactis* are taught in the prior art. Moreover, no homolog to lacR, the repressor found in the operon of *L. delbrueckii* subsp. *lactis* described in the instant specification, is taught by Leong-Morgenthaler *et al*. In fact, Germond *et al*. particularly note that ONLY the subspecies *lactis* contains the lacR repressor protein in the lac operon of all the *L. delbrueckii* subspecies."

***Conclusion***

24. Claims 20, 21, 27, 28, 31, and 38 are allowed. Claims 22, 24, 29, 35, and 36 are objected to. Claims 23, 25, 26, 30, 32-34, and 37 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
September 9, 2003